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IN THE

Supreme Court of the United States

DUKE UNIVERSITY,

Petitioner,

v.

JOHN M.J. MADEY,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF FOR ASSOCIATION OF AMERICAN MEDICAL COLLEGES, ET AL., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

JOSEPH A. KEYES, JR.
ASSOCIATION OF AMERICAN MEDICAL COLLEGES
2540 N Street, N.W.
Washington, D.C. 20037
(202) 828-0555

KEITH A. JONES
Counsel of Record
BECK, REDDEN & SECREST
1221 McKinney Street
Houston, TX 77010
(713) 951-3700

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

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QUESTION PRESENTED

Whether universities are precluded from asserting the federal common law experimental use exemption from liability for patent infringement merely because their scientific research programs serve legitimate educational purposes.*

* The thiry-one *amici curiae* are listed in the Appendix, *infra.*

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BRIEF FOR ASSOCIATION OF AMERICAN MEDICAL COLLEGES, ET AL., AS *AMICI CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF *AMICI CURIAE* [1]

Amici curiae represent universities whose faculties engage in scientific research. They consist of the **Association of American Medical Colleges,** whose membership includes 125 medical schools, nearly 400 teaching hospitals and health systems, and 92 academic societies with an aggregate indi-

[1] The following representations are made pursuant to Sup. Ct. R. 37: The parties have consented to the filing of this brief; no counsel for either party authored any portion of this brief; no persons other than *amici curiae* made any monetary contribution to the preparation or submission of this brief.

vidual membership of approximately 100,000; the **American Council on Education,** representing approximately 1800 colleges and universities and serving as a forum for consideration of higher education issues of national importance; the **Association of American Universities**, whose 62 members include most of the nation's leading public and private research universities; the **National Association of State Universities and Land Grant Colleges**, representing public universities from all 50 states; the **Council on Governmental Relations**, an association of 150 research-intensive universities devoted to maximizing the scientific benefit from federal investment in academic research; the **Association of University Technology Managers**, a non-profit organization of approximately 3300 professionals dedicated to issues related to technology transfer; **Public Citizen, Inc.**, a public interest advocacy group; the **Howard Hughes Medical Institute**, which supports research conducted by faculty with joint appointments at universities and the Institute; and the following individual colleges, universities, and medical schools: **Baylor College of Medicine; The Regents of the University of California; Carnegie Mellon University; Emory University; University of Florida; Georgetown University; The George Washington University; Iowa State University of Science and Technology; Johns Hopkins University; University of Kentucky; University of Maryland; Massachusetts Institute of Technology; Mount Sinai School of Medicine; New York University; The University of North Carolina at Chapel Hill; University of Pittsburgh; Rutgers, the State University of New Jersey; University of Texas at Austin; Texas A&M University; Vanderbilt University; University of Washington; Washington State University; and Yale University.**

Universities spent more than $30 billion on scientific research and development in calendar year 2000. National Science Foundation, *Science and Engineering Indicators*

2002, App. Table 5-2 (2002). The *amici curiae* all directly engage in or actively support such university-based scientific research. The decision by the Federal Circuit in this case, however, poses a serious threat not only to the viability of many individual academic research projects but also to the vitality of academic scientific research generally. The *amici curiae* have an obvious and very strong interest in this case and in the reversal of the decision below.

INTRODUCTION

The Federal Circuit's decision limiting the scope of the common law experimental use exemption from liability for patent infringement is of immense importance to all universities whose faculties engage in scientific research. By effectively eliminating the exemption for even noncommercial academic scientific research, the decision erects a significant roadblock to the advancement of science. The *amici curiae* are deeply disturbed by this ruling. *See* Note, "Universities Ask Supreme Court to Reverse Patent Ruling," 299 Science 26 (January 3, 2003). In the past, university-based research has been crucial to scientific progress on almost every front. The decision below threatens to stifle that research and thereby endanger this nation's continued leadership in science and technology. The question presented by this case is vital to the nation's scientific wellbeing.

Universities will be forced to bear substantial administrative and financial costs to cover patent searches, infringement opinions, licensing agreements, and the inevitable litigation that will be engendered by the Federal Circuit's new rule of patent law. The money diverted into such uses will no longer be available for actual research. As a result of these additional costs and also the associated delays occasioned by patent searches and the negotiation of licenses, university-based research programs will be curtailed and research projects abandoned. In many situations patent holders are likely to use the court's ruling as a basis for imposing onerous

financial or nonfinancial licensing terms or even as a means of barring entire lines of what they may view as potentially competing scientific research. These developments place in jeopardy the research plans and activities of thousands of science graduate students and faculty researchers.

There is a serious risk that the Federal Circuit's decision will significantly impede this nation's scientific progress. In the end, the burden will be borne by the general public in its capacity as consumer and beneficiary of the scientific advances the patent system is intended to foster. The *amici curiae* ask this Court to grant review and reverse in order to avert the drastic consequences that otherwise can be expected to flow from the decision below.

SUMMARY OF ARGUMENT

The experimental use exemption historically has protected noncommercial research from claims of patent infringement; although prior to this case there had been virtually no litigation with respect to academic scientific research *per se*, the scientific community had every reason to believe that the exemption would protect noncommercial academic research just as it protected other noncommercial research.

The decision below radically departs from prior law. Without inquiring into the commercial or noncommercial nature of the research at issue, the Federal Circuit announced that universities are ineligible to claim the experimental use exemption for the paradoxical reason that the scientific research in which they are engaged serves legitimate educational purposes. The obvious result of this ruling is to deny the experimental use exemption with respect to all scientific research conducted at universities and other nonprofit research institutions, even when that research is manifestly noncommercial.

The Federal Circuit's holding in this case will have a significant chilling effect on all academic scientific research,

and especially that in biotechnology and biomedicine. Depriving university scientists of the experimental use exemption will directly and significantly increase the cost of basic research, the great majority of which is supported by competitively awarded federal funds. In many situations, the unanticipated need to negotiate licenses before initiating or while in the midst of research projects may forestall or seriously disrupt ongoing research. In some circumstances, patent holders may refuse licenses and thus bar research from going forward at all. The *amici curiae* are gravely concerned that, if the experimental use exemption is no longer available, the proliferation of patents on upstream tools for biotechnological, biomedical, and advanced electronic research will have a very adverse effect on basic and applied downstream research activity at universities and other nonprofit research institutions.

This Court should grant review to restore the federal common law experimental use exemption to its traditional role as a safe haven for noncommercial scientific inquiry.

ARGUMENT

A. The Experimental Use Exemption Historically Has Protected Noncommercial Research From Claims Of Patent Infringement

"[T]he courts have long recognized . . . that a purely 'experimental use' of a patented invention, with no commercial purpose, should be exempt from infringement liability." R. Eisenberg, "Patents and the Progress of Science: Exclusive Rights and Experimental Use," 56 U. Chi. L. Rev. 1017, 1018-19 (1989). This experimental use exemption, which was first articulated by Justice Story in *Whittemore v. Cutter,* 29 F. Cas. 1120 (C.C.D. Mass. 1813), serves a purpose somewhat analogous to that of the fair use doctrine of copyright law. J. Mueller, "No 'Dilettante Affair': Rethinking the Experimental Use Exception to Patent Infringement

for Biomedical Research Tools," 76 Wash. L. Rev. 1, 42-43 (2001); M. O'Rourke, "Toward a Doctrine of Fair Use in Patent Law," 100 Colum. L. Rev. 1177, 1192-94 (2000). The exemption ultimately is grounded in the same constitutional rationale as the patent system itself: scholarly freedom to use and build upon patented advances in the course of noncommercial scientific inquiry is of critical importance to "the Progress of Science and useful Arts." U.S. Const., Art 1, Sec. 8. *See* I. Feit, "Biotechnology Research and the Experimental Use Exception to Patent Infringement," 71 J. Pat. & Trademark Off. Soc'y 819, 839 (1989).

In determining the type of "experimental use" entitled to exemption, courts historically drew the line between commercial and noncommercial research. Noncommercial research was protected. For example, the exemption covered the federal government's use of a patented alloy "for experimental purposes." *Chesterfield v. United States,* 159 F. Supp. 371, 375 (Ct. Cl. 1958). In the only reported case involving an academic institution (the Colorado School of Mines) the court explained that the "making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement." *Ruth v. Stearns-Roger Mfg. Co.,* 13 F. Supp. 697, 713 (D. Colo. 1935), *rev'd on other grounds,* 87 F.2d 35 (10th Cir. 1936).

In contrast, commercial research was not protected. A major landmark in this regard was *Roche Products, Inc. v. Bolar Pharmaceutical Co.,* 733 F.2d 858 (Fed. Cir. 1984), where the Federal Circuit held that the experimental use exemption does not cover one pharmaceutical company's use of another's patented drug for the purpose of performing tests necessary to obtain regulatory approval of its own competing version of the drug. The court explained, "[w]e cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,'

when that inquiry has definite, cognizable, and not insubstantial commercial purposes." *Id.* at 863. *See also Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) (holding, in a patent dispute between two commercial competitors, that the experimental use exemption does not protect research performed "expressly for commercial purposes").

"[A]fter *Roche,* scientists engaged in research and development having more than negligible commercial purpose could no longer rely on the experimental use doctrine." J. Mueller, *supra*, 76 Wash. L. Rev. at 24. Yet with its emphasis on the distinction between commercial and noncommercial purposes, *Roche* appeared to confirm that genuinely noncommercial scientific research undertaken by university scientists or government researchers remained protected by the experimental use exemption. As one writer put it shortly after *Roche*, "[f]ew would deny the experimental use exception for research on patented technology performed at a university in furtherance of its educational function." R. Hantman, "Experimental Use as an Exception to Patent Infringement," 67 J. Pat. & Trademark Off. Soc'y 617, 633 (1985).

Subsequent developments provided further support for the view that traditional noncommercial scientific research falls well within the protective scope of the experimental use exemption. Congress, believing that *Roche* had improperly narrowed the exemption, enacted the Drug Price Competition and Patent Term Restoration Act of 1984, 35 U.S.C. § 271(e), reversing the result in that case and thereby extending protection even to certain specified commercial research activities. The Federal Circuit seemingly took this to heart, giving the new statute a broad reading in *Eli Lilly & Co. v. Medtronic, Inc.*, 872 F.2d 402, 405-06 (Fed. Cir. 1989), *aff'd*, 496 U.S. 661 (1990).

This history afforded university communities and patent holders alike strong reason to believe that Justice Story's experimental use exemption continued to protect noncommercial academic research from claims of patent infringement. A recent study, based upon "70 interviews with personnel at biotechnology and pharmaceutical firms and universities," confirms that "university researchers, to the extent that they are doing noncommercial work, are largely left alone" and that in those rare instances when universities received letters alleging infringement "the typical response was effectively to ignore such letters and inform the [patent] holder that the university was engaged in research, did not intend to threaten the firm's commercial interests, and would not cease its research." J. Walsh, A. Arora, and W. Cohen, "The Patenting and Licensing of Research Tools and Biomedical Innovation," 2, 35, in National Academy of Sciences, *Patents in the Knowledge-Based Economy* (2003).

B. The Decision Of The Federal Circuit In This Case Radically Departs From Prior Law By Denying The Experimental Use Exemption To All Academic Scientific Research, Even When That Research Is Manifestly Noncommercial

The Federal Circuit in this case eschewed any inquiry into whether the research at issue was genuinely noncommercial. Instead, the court issued a broad ruling effectively denying the experimental use exemption to all university-based research in all circumstances.

In an opinion frankly hostile to the experimental use exemption, the Federal Circuit essentially disavowed prior law with its clearly drawn distinction between commercial and noncommercial research. The court held, instead, that the exemption is not available to nonprofit universities *because scientific research at those universities serves legitimate educational purposes*:

> [M]ajor research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. . . .
>
> In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense.

Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

This decision is both bad law and bad policy. The distinction between commercial and noncommercial research always has been the touchstone of the experimental use exemption. Indeed, when he first articulated the doctrine in *Whittemore* Justice Story was specifically contrasting "philosophical experiments" with "use [of the patented invention] for profit." 29 F. Cas. at 1121. Scientific research directed toward "educating and enlightening students and faculty," *Madey*, 307 F.3d at 1362, is exactly the sort of activity embraced by the early nineteenth-century expression "philosophical experiments." L. Bruzzone, "The Research Exemption: A Proposal," 21 AIPLA Q. J. 52, 60 (1993).

Noncommercial academic scientific research logically lies at the very core of the experimental use exemption. R. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," 97 Yale L.J. 177, 223 (1987). Yet the Federal Circuit appears now to have made the exemption inapplicable to virtually all truly serious scientific research. This creates a substantial likelihood that "the patent system

[will] function to thwart the very innovation that it is intended to foster." M. O'Rourke, *supra*, 100 Colum. L. Rev. at 1180.

The Federal Circuit was led astray by language in *Pitcairn v. United States,* 547 F.2d 1106 (Ct. Cl. 1976), *cert. denied,* 434 U.S. 1051 (1978), holding that the experimental use exemption did not apply when the government was merely engaged in testing newly purchased helicopters to make sure that they worked properly. There can be no quarrel with the result in *Pitcairn*: routine testing of equipment is not truly scientific research and need not be protected as "experimental use." In justifying that unexceptionable result, however, the *Pitcairn* court explained, somewhat infelicitously, only that the government's use of the helicopters had been "in keeping with the legitimate business of the using agency." *Id.* at 1125-26.

The expression "legitimate business" was seized upon by the Federal Circuit in this case without paying due attention to context. The *Pitcairn* court had employed that expression offhandedly, as a way of indicating that the government was not actually engaged in scientific research but rather was simply ascertaining, before placing its helicopters in regular use, that they were capable of being operated in the manner intended. The Federal Circuit here misread *Pitcairn,* making the inquiry focus on the relationship of the patented invention's use to the defendant's "business" rather than on whether that use genuinely constitutes noncommercial scientific research. The court lost sight of the values furthered by the experimental use exemption and, in doing so, constructed an apparently absolute barrier to a claim of exemption by any modern research university (or by any government agency or other nonprofit organization, for that matter) engaged in the "business" of noncommercial scientific research.

C. The Decision Below Will Have A Significant Chilling Effect On Academic Scientific Research, Especially In Biotechnology And Biomedicine

"[A] significant portion of scientific innovation occurs in university, government, and private non-profit environments . . . ." E. Barash, "Experimental Uses, Patents, and Scientific Progress," 91 Nw. U. L. Rev. 667, 696 (1997). Much of this scientific innovation results from basic research that is directed toward the general acquisition and dissemination of scientific knowledge and has no explicit commercial objective.

Universities and university scientists—to the extent they consider the issue at all—assume that their noncommercial research is exempt. *See* M. Thayer & R. De Liberty, "The Research Exemption to Patent Infringement: The Time Has Come for Legislation," 4 J. Biolaw & Bus. 1, 2 (2000). They "rarely check the patent literature to determine whether their proposed research will infringe on any patents." E. Barash, *supra*, 91 Nw. U. L. Rev. at 698. Nor are they in a position to do so. "While corporations have legal departments geared towards answering potential legal quagmires, universities do not have the infrastructure to render routine opinion work to researchers." *Id.* Universities are "ill equipped to handle multiple transactions for acquiring licenses to use research tools." M. Heller & R. Eisenberg, "Can Patents Deter Invention? The Anticommons in Biomedical Research," 280 Science 698, 700 (1998).

The decision below works a drastic change in the legal environment. Depriving university scientists of the experimental use exemption will directly and significantly increase the cost of basic research even when patent holders are willing to make licenses available:

> [L]icensing patented inventions used in basic research poses special problems. The need to obtain licenses would add significant administrative and financial bur-

> dens to researchers in fields where patent protection is widespread. Most research builds on prior discoveries. If a significant number of these are patented, obtaining licenses on each would generate mounting royalty and transaction costs.

S. Michel, "The Experimental Use Exception to Infringement Applied to Federally Funded Inventions," 7 High Tech. L. J. 369, 398 (1992). The need to allocate scarce university resources to the processing of scientifically unproductive administrative and legal paperwork will involve a significant diversion of funds away from educationally more important activities, including actual scientific research.

There will be not only greater costs but longer delays in getting research started if, indeed, patent holders permit it to be undertaken at all. The need to obtain licenses will constitute an initial and major hurdle in the path of many projects. "Delays in negotiating multiple agreements to use patented processes, reagents, and gene fragments could stifle the creative give-and-take of academic research." M. Heller & R. Eisenberg, *supra*, 280 Science at 700.

The added cost of conducting patent searches and paying for licenses, and the concomitant delays in launching research projects, are not the only, and may not be the worst, problems facing universities and their researchers in the wake of the decision below. The unanticipated need to acquire licenses in the midst of a project can seriously disrupt if not entirely derail ongoing research. It simply "is not practical for researchers to wait for a patent infringement evaluation each time they perform a basic laboratory technique." I. Feit, *supra*, 71 J. Pat. & Trademark Off. Soc'y at 822. Research does not follow in a straight line. One line of inquiry will often open up an entirely new line of inquiry not contemplated at the outset. To halt research in mid-stream for months or years in the face of an unanticipated need to obtain a license—or even worse, to be required to abandon the

research altogether upon the denial of a license—will have a very serious deleterious effect on the competitive advantage American universities' research programs currently have in the world. *See* R. Eisenberg, *supra*, 56 U. Chi. L. Rev. at 1056.

In some circumstances, the absence of an experimental use exemption may make it altogether impossible to undertake a planned research project. As the National Institutes of Health has observed, "[p]rogess in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories throughout the government, academia, and industry." 64 Fed. Reg. 72090, 72093 (1999). It follows that "intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research . . . ." *Id.* at 72092. The problem is that "some patent holders will undoubtedly object to the use of their inventions in subsequent research and, in the absence of an experimental use exemption, might use their exclusive rights to stop valuable research from proceeding." R. Eisenberg, *supra*, 56 U. Chi. L. Rev. at 1072. This "could undermine a critical mechanism of the scientific community for facilitating the progress of science." R. Eisenberg, *supra*, 97 Yale L.J. at 225.

Even before the decision below, many commentators were concerned that the Federal Circuit's emphasis in *Roche* on the narrowness of the experimental use exemption "could have significant chilling effects on research efforts." L. Bruzzone, *supra*, 21 AIPLA Q. J. at 65; *see also, e.g.*, S. Michel, *supra*, 7 High Tech. L.J. at 389-90; E. Barash, *supra*, 91 Nw. U. L. Rev. at 698. By effectively abolishing the experimental use exemption for all academic scientific research, the decision below magnifies the problem enormously. The Federal Circuit's opinion in this case will have a very damaging chilling effect on all university-based scientific research.

This chilling effect will be felt in all scientific areas where patent protection has been granted to intellectual advances that may form part of the foundation for further research, including chemistry, physics, and advanced electronics. The problem may be at its most severe, however, in biotechnology and biomedicine:

> The explosion of biotechnological and biomedical research and development in the United States in the past twenty years, with a corresponding increase in patenting activity, particularly in the area of genomics, has concomitantly heightened difficulties of access to and dissemination of patented research tools. Burgeoning research and development will require ever-greater numbers of proprietary tools, giving rise to transaction costs associated with acquiring the right to use each tool. In some cases, the patentee may refuse to license the research tool altogether.

J. Mueller, *supra*, 76 Wash. L. Rev. at 5-7. The *amici curiae* are gravely concerned that the decision below will encourage patent holders to assert claims in a manner that will impede or altogether frustrate university scientists' ability to make further basic advances in critical areas of biotechnology and biomedicine.

The past two decades have seen "a spiral of overlapping patent claims in the hands of different owners, reaching ever further upstream in the course of biomedical research." M. Heller & R. Eisenberg, *supra*, 280 Science at 698. "Patented research tools" now include such things as "cell lines, monoclonal antibodies, reagents, animal models, growth factors, combinatorial chemistry and DNA libraries, clones and cloning tools." 64 Fed. Reg., *supra*, at 72092 n.1. For example, "[m]any of the pioneering developments in basic laboratory methods necessary for recombinant DNA experiments have been patented." I. Feit, *supra*, 71 J. Pat. & Trademark Off. Soc'y at 820.

Many patents in the field of biotechnology do not cover products or even methods but are essentially informational in nature, covering such matters as anonymous gene fragments and protein crystalline coordinates. *See, e.g.*, M. Heller & R. Eisenberg, *supra*, 280 Science at 699. For example, patents have been granted on the identification of "small segments of complimentary DNA [that] have no presently known utility [but] are believed to be useful as probes in searching for corresponding full-length genes." J. Mueller, *supra*, 76 Wash. L. Rev. at 13-14. The inability to work with such information could blunt the promise of the remarkable achievement of the Human Genome Project by crippling follow-on basic research in fields such as genomics and proteomics (the study of proteins and their functions within the cell) and significantly impair academic researchers' ability to achieve important new breakthroughs in biomedical science.

The magnitude of the problem is suggested by recent action taken by Hoffman-La Roche Corporation ("Roche") with respect to its patents over the thermostable enzyme Thermus aquaticus YTl DNA polymerase ("Taq") and polymerase chain reaction ("PCR"). Taq is a basic biotechnology tool "widely used in DNA sequencing." J. Mueller, *supra*, 76 Wash. L. Rev. at 2. PCR is "the revolutionary DNA amplification process that utilizes Taq." *Id.* at 3. In 1995,

> Roche accused more than forty U.S. universities and research institutes (including Harvard, Stanford, Massachusetts Institute of Technology, the Salk Institute, the Scripps Research Institute, and the National Cancer Institute) and more than 200 individual scientists of infringing these patents. . . . Roche officials professed no concern about the use of Taq for 'pure research' purposes, but stated that they felt compelled to take

> action against those scientists engaged in what Roche termed 'highly practical' research with potential profit-making potential.

Id. Roche and other similarly situated patentees may be emboldened by the decision below to extend their aggressive patent enforcement to noncommercial "pure research" as well. *See id.* ("a Roche spokesperson . . . warned that she 'wouldn't want to predict what action Roche would take relative to any patent . . . in the future'"). This poses a major threat to the continued vitality of noncommercial academic biotechnological and biomedical research programs.

This nation has benefited enormously in the past from noncommercial academic scientific research, as more discoveries and greater understanding of the unknown have pointed toward and facilitated commercial research leading to new and socially beneficial products and applications. The Federal Circuit's decision threatens to retard this process significantly. Even before the decision below, there was grave concern in the scientific and public policy communities that "the proliferation of patents on 'upstream' basic tools of biotechnological and biomedical research will stymie the development of . . . downstream application[s]." J. Mueller, *supra*, 76 Wash. L. Rev. at 7. The denial of experimental use protection for noncommercial academic scientific research will make a difficult situation much worse.

D. This Court Should Grant Review To Restore The Federal Common Law Experimental Use Exemption To Its Traditional Role As A Safe Haven For Noncommercial Scientific Inquiry

This Court should grant the petition for certiorari and hold that universities are not precluded from asserting the experimental use exemption merely because their research programs serve legitimate educational purposes.

The issue clearly is important. Respondent may argue, however, that certiorari should be denied because there is no conflict among the circuits and the matter is interlocutory. In the circumstances of this case, those factors do not genuinely militate against review.

The Federal Circuit has exclusive appellate jurisdiction over cases arising under federal patent law. 28 U.S.C. § 1295(a)(1). Thus there is and will be no conflict among the circuits on the reach of the experimental use exemption. But this does not mean that this Court should defer to the Federal Circuit's presumed expertise and leave standing the harmful and misguided ruling below. As Justice Stevens recently noted, "decisions by courts with broader jurisdiction will provide an antidote to the risk that the specialized court may develop an institutional bias." *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 122 S.Ct. 1889, 1898 (2002) (concurring). This case presents an issue of federal common law that is too important to be left to a specialized patent court; this Court, with its broader perspective, should intervene to resolve the issue.

Although the case nominally is interlocutory, there is nothing further to be done on remand with respect to the experimental use exemption. The Federal Circuit has noted that Duke University's scientific research projects "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty" and has held that any act "in furtherance of the alleged infringer's legitimate business . . . does not qualify for the very narrow and strictly limited experimental use defense." *Madey*, 307 F.3d at 1362. As a practical matter, that forecloses Duke from asserting the experimental use defense on remand. Moreover, even if on remand Duke were to prevail on other grounds, the Federal Circuit's ruling with respect to experimental use still would stand as the radically new and disruptive law of the land.

As long as it does remain standing, the Federal Circuit's ruling will raise serious concerns and cause serious harm to American universities, to the academic scientific research community, and to "the Progress of Science and useful Arts." U.S. Const., Art 1, Sec. 8. The case warrants immediate plenary review.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

JOSEPH A. KEYES, JR.
ASSOCIATION OF AMERICAN MEDICAL COLLEGES
2540 N Street, N.W.
Washington, D.C. 20037
(202) 828-0555

KEITH A. JONES
Counsel of Record
BECK, REDDEN & SECREST
1221 McKinney Street
Houston, TX 77010
(713) 951-3700

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